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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,278	11/13/2000	Michael Reggeline	147/49227	2959

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/700,278

Applicant(s)

REGGELIN ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17,18,20-22,24,25,27-29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17,18,20-22,24,25,27-29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

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1. Claims 17, 18, 20-22, 24, 25, 27-29, 31-33 are pending. Claims 1-16 have been canceled according to the preliminary amendment filed on 11-13-2000. Claims 26, 30 have been canceled according to the amendment filed on 5-14-2002. Claims 19 and 23 have been canceled according to the amendment filed on 10-11-2002.

***Claim Rejections - 35 USC § 102***

3. The 35 U.S.C. 102(a) rejection for claim 27 over Bolte (PTO-1449) is maintained for reasons for record.

The Bolte reference expressly anticipates all of the elements of the claimed invention, the reference is presumed to be operable. The burden is on the applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See MPEP 716.07.

Applicant submits that Bolte has not specifically described the method of making the compound. However, the process of making the compound is well known in the art as described for the analogous tetrahydrofurans (Reggelin, Liebigs Ann/Recueil 1997, 181-1886, PTO-1449). Bolte therefore contains an "enabling disclosure" since the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). See MPEP 2121.

Applicant argues that the intermediate compound Xa of instant claim 27 is not obtained by the same method of Reggelin since the instant process claim 17 has been amended to incorporate the limitation of a base-labile protecting group, which is split off by a base reagent. Such a process is not described by Reggelin. However, there is no requirement that the prior art compound has to be made by the same method as the inventive compound.

***Claim Rejections - 35 USC § 103***

4. The 35 U.S.C. 103(a) rejection for Claims 27-28 over Bolte (PTO-1449) in view of Greene is maintained for reasons of record.

The Bolte reference renders obvious all of the elements of the claimed invention, the reference is presumed to be operable. The burden is on the applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See MPEP 716.07.

Applicant submits that Bolte has not specifically described the method of making the compound. However, the process of making the compound is well known in the art as described for the analogous tetrahydrofurans (Reggelin, Liebigs Ann/Recueil 1997, 181-1886, PTO-1449). Bolte therefore contains an "enabling disclosure" since the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). See MPEP 2121.

Applicant argues that the intermediate compound Xa of instant claim 27 is not obtained by the same method of Reggelin since the instant process claim 17 has been amended to incorporate the limitation of a base-labile protecting group, which is split off by a base reagent. Such a process is not described by Reggelin. However, there is no requirement that the prior art compound has to be made by the same method as the inventive compound.

5. The 35 U.S.C. 103(a) rejection for Claims 17-25, 31-33 over Claims 17-25, 31-33 over Chu (5252747) and Reggelin I (Liebigs Ann/Recueil, 1997, PTO-1449) and Reggelin II (J. Am. Chem. Soc. 1996) and Bolte (PTO-1449) in view of Greene is withdrawn upon reconsideration in view of the amendment incorporating the limitation of a base-labile amino protecting group in the definition of R13 in step a), the use of a base reagent in step b) and the use of samarium (II) iodine for the reductive cleavage of the sulfonimidoyl-alkyl bond in step c), thereby setting a demarcation from the prior art of record. Motivation to modify the prior art process to arrive at the instant process is lacking.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18, 20-22, 24-25, 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 17, step c) is for the production of compound of formula Ia. However, only the steps leading to production of compound of formula Ib are described. The step converting Ib to Ia is missing. Or is Ia is equivalent to Ib? Clarification is required.

b. Claim 21, the 'base reagent' has no antecedent basis in the base claim 20. Furthermore, the term 'comprises' in 'the base reagent comprises' is open ended and is therefore indefinite.

c. Claim 27, definition of  $R^{801}$ , 'p-biomophenyl' should be 'p-bromophenyl'.

d. The compound of formula Xa in Claim 31 is improperly dependent on the process claim 17. It should depend on the compound claim 27.

The rejection is applicable to claims dependent on the above claims.

***Allowable Subject Matter***

7. The subject matter of process claims 17, 18, 20-22, 24, 25, 31-33 is allowable. See paragraph 5 above.

The intermediate compound claims 27-29 would be allowable if the prior art compound of Bolte is excluded by the proviso that when  $n=0$ ,  $R^{801}$  is not phenyl-lower alkyl. Alternatively, a 131 declaration predating the reference would remove Bolte as prior art under 102(a).

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*Conclusion*

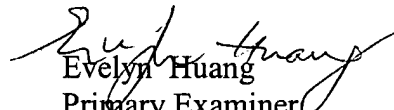
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

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January 10, 2003